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RUEAUSA/DEPT OF HHS WASHINGTON DC
RUEHPH/CDC ATLANTA GA PRIORITY 0001
RUEHRC/DEPT OF AGRICULTURE WASHINGTON DC
RUEHOT/AMEMBASSY OTTAWA PRIORITY 0045
RUEHMD/AMEMBASSY MADRID PRIORITY 0011
RUEHMC/AMCONSUL MONTERREY 9626

UNCLAS SECTION 01 OF 02 MONTERREY 000397

SENSITIVE
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DEPARTMENT PASS OES/IHB

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SUBJECT: MONTERREY TEC ANNOUNCES POTENTIALLY GROUNDBREAKING NEW A/H1N1 INFLUENZA VACCINE

REF: A) MEXICO 3044

MONTERREY 00000397  001.2 OF 002

¶1. (SBU) Summary. Four days before POTUS' October 23 declaration of a national emergency in the face of the growing influenza pandemic, researchers at Monterrey TEC's FEMSA Biotechnology Center announced the development of a new type of A/H1N1 influenza vaccine with the potential to solve current shortages which have created vulnerabilities in the public health systems of both the U.S. and Mexico. The vaccine has yet to undergo human trials, but in an October 23 conversation with EconOff, the Monterrey TEC's Dean of Biotechnology said that if successful, it could be produced in as early as six to eight months. The Rector of Monterrey TEC states that if the vaccine passes clinical trials, the university plans to turn the formula over - free of charge - to Mexican private sector vaccine manufacturers so that doses can be produced for as low a cost as possible. End summary.

¶2. (U) On October 19, researchers at Monterrey TEC's FEMSA Biotechnology Center announced to local media that researchers had developed a novel vaccine for the A/H1N1 influenza virus. Researchers described this vaccine as "paradigm breaking" because of the unique process by which it can be produced rapidly, massively and inexpensively.

¶3. (SBU) Dr. Manuel Zertuche Guerra, Dean of TEC's Division of Biotechnology and Food Engineering, confirmed the media report to EconOff on October 23. He explained that traditional flu vaccines are produced by cultivating an influenza virus in the yolk of a fertilized chicken egg. The virus is then extracted and chopped into pieces, creating the vaccine. The FEMSA Biotechnology Center's new procedure creates this new vaccine by using an innovative - and far less laborious - process which uses cell cultures to reproduce the proteins affixed to the outside of the virus's shell, instead of the entire virus. It is these proteins which actually trigger the body's autoimmune response.

¶4. (SBU) Zertuche emphasized that while the vaccine has proven safe and effective at the molecular and cellular levels, to date it has only been tested in animals, and is still undergoing trials. He believes that the center needs two more months to prepare the vaccine for submission to Mexico's Federal Commission for the Protection against Sanitary Risks (COFEPRIS) for approval of human trials. While stressing that it is very difficult to predict a timeline - and emphasizing that in the face of a genuine health crises testing and approval might even

be accelerated - he suggested that 6-8 months from the present date was a realistic estimation of the time required to win final approval for this vaccine. If approved, he claims that the vaccine could be produced at existing pharmaceutical facilities and ready for public distribution within 2-3 weeks. Separately, on October 26 Carlos Cruz, Monterrey TEC Rector for Innovation and Development, told Consul General that if human trials proved successful, the university would make the formula available to Mexican vaccine manufacturers free of charge so as to speed the production of low-cost vaccines.

Delay in Receipt of Key Authorization
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¶5. (SBU) Zertuche was eager to discuss the FEMSA Biotechnology Center's contribution to national and international efforts to contain this virus because he believed that, with U.S. and other international support, the Center could make a greater contribution. Zertuche said he and his team felt frustrated last April when authorities initially declared an epidemic. According to him, within 72 hours of that declaration, the U.S. Center of Disease Control (CDC) - working with Biogen Idec labs in San Diego - delivered to Mexican authorities the "primer," the sequence of ribonucleic acid (RNA) used to replicate a virus, key in developing a diagnostic tool to identify the particular strain of influenza to which the epidemic was attributed. The CDC made the protocol immediately available to interested labs. In order to actually develop a diagnostic procedure, the FEMSA Biotechnology Center needed both the primer and the protocol. However, Zertuche said it took the GOM approximately one month to verify that his facility had the laboratories, equipment, and training necessary to handle the primer safely. "At a critical moment," he noted, "we were not ready." (Comment: Zertuche admitted that the lab had not been accredited when the CDC sent the primer to Mexico. It is accredited now, and he does not anticipate the same problem in the case of future epidemics. End comment.)



Superior Diagnostic Tests
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¶6. (SBU) Zertuche pointed out that Monterrey TEC's FEMSA Biotechnology Center is one of only five Mexican laboratories capable of handling diagnostics and research on this kind of virus, and one of only two or three currently dedicated to doing so. Since last May, the center has completed more than 800 diagnostic tests for the A/H1N1 virus. It has developed several primers of its own, which are undergoing tests at St. Jude Children's Research Hospital in Tennessee. Zertuche believes that his laboratory's diagnostic processes are both more sensitive and economical than those provided by the CDC.

Questionable Statistics, Better Surveillance
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¶7. (SBU) Zertuche expressed confidence in GOM statistics confirming deaths caused by the A/H1N1 virus, but had less confidence in other H1N1 related-statistics, including rates of infection. He observed that current diagnostic tests are expensive, and while the test's positive identifications of the virus are generally reliable, it has a high incidence of false negatives. The FEMSA Biotechnology Center's Epidemiological Vigilance Unit has been working to collect more accurate data: since August 30, the unit has tracked over five thousand cases of individuals in Metropolitan Monterrey who have generated antibodies to the A/H1N1 virus, but display no symptoms.

More Resources, Collaboration Sought
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¶8. (SBU) While Zertuche believes that this information will develop a more accurate picture of the virus' prevalence and impact, he believes that Mexico should devote resources to a dedicated surveillance facility, like that of St. Jude

Children's Research Hospital, in order to track threatening viruses' lethality, mutations and modes of transmission. He added that Monterrey TEC had approached the Pan American Health Organization in search of resources to expand the FEMSA Biotechnology Center's facilities, and has received a financial commitment from the Spanish Government for the same purpose.

¶9. (SBU) According to Zertuche, his team has a collaborative agreement with University of Texas' M.D. Anderson Cancer Center, and attorneys are working with St. Jude Children's Research Hospital to create the confidentiality agreements required to release the kind of detailed information useful to scientific colleagues in the U.S. Dr. Mario Moises Alvarez, Director of the FEMSA Biotechnology Center, confirmed in a later conversation that his center was negotiating with the Canadian Government to form a collaborative agreement with its National Microbiology Laboratory as well. He said that he was particularly interested in working with Canadian Light Source, Canada's national synchrotron research facility, to analyze the structure of the proteins used in creating the A/H1N1 vaccine.

Comment
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¶10. (SBU) Zertuche is an eloquent advocate for the FEMSA Biotechnology Center. He was particularly passionate in his appeal for U.S. support and somewhat guarded in his explanation of current research initiatives, in particular regarding details about the new vaccine development process. His reticence was most likely due to his desire to guard as yet unpatented trade secrets (the FEMSA Biotechnology Center has applied for a domestic patent).

¶11. (SBU) Mexico, like the U.S., currently faces an A/H1N1 vaccine shortfall. French pharmaceutical firm Sanofi Pasteur has only delivered 10 million of the 30 million doses the GOM ordered, due to increased worldwide demand (Reftel A). Any new technique which could exploit current infrastructure to produce sufficient vaccine quickly could mitigate a serious risk to public health.
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